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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,705	07/12/2001	Daniel P. Bednarik	PF138P1C1	8314

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/902,705

Applicant(s)

BEDNARIK ET AL.

Examiner

Delia M. Ramirez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-31, 33-37, 64-68 and 70-126 is/are pending in the application.
- 4a) Of the above claim(s) 75 and 76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-31, 33-37, 64-68, 70-74, 77, 80, 83-104, 106, 108-115 and 117 is/are rejected.
- 7) ☒ Claim(s) 78, 79, 81, 82, 105, 107, 116 and 118 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Application

Claims 27-31, 33-37, 64-68 and 70-126 are pending.

Applicant's amendment of claims 27, 29, 64, 66, addition of claims 77-126, and cancellation of claims 1-26, 32, 38-63, 69, in a communication filed on 3/22/2004 are acknowledged.

As indicated in a previous Office Action mailed on 12/04/2003, claims 75-76 were withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to an invention non-elected with traverse in a communication filed on 9/17/2003. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 3/22/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

2. Acknowledgement is made of a submission of corrected Figure 2 in a communication filed on 3/22/2004.

Claim Objections

3. Claims 78-83, 92-95, 104-107, 116-119 is objected to due to the recitation of "polynucleotide sequence encoding a polypeptide sequence is (x)". For clarity and consistency, it is suggested that the term be replaced with "polynucleotide sequence encoding the polypeptide is (x)". It is noted that claims

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77, 91, 103, and 115 refer to “a polynucleotide sequence encoding a polypeptide selected from the group consisting of” and there is no “polypeptide sequence” recited. Appropriate correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 77, 80, 83-90, 115, 117, 119-126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

6. Claims 77, 80, 83-90, 115, 117, 119-126 are directed to (1) nucleic acids comprising a polynucleotide encoding amino acids 59-73 of SEQ ID NO: 2 or the purine binding motif of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 75844, (2) a method to recombinantly produce the proteins encoded by the nucleic acids of (1), and (3) a host cell comprising the nucleic acids of (1). The Examiner is unable to locate adequate support in the specification for nucleic acids comprising a polynucleotide encoding amino acids 59-73 of SEQ ID NO: 2 or the purine binding motif of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 75844, a host cell comprising said nucleic acids, or a method to recombinantly produce the proteins encoded by the nucleic acids. Thus there is no indication that the nucleic acids, methods, and host cells of claims 77, 80, 83-90, 115, 117, 119-126 were within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

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7. Claims 27-31, 33-37, 64-68, 70-74 remain rejected and new claims 77, 80, 83-102, 115, 117, 119-126 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection has been discussed at length in a previous Office Action mailed on 12/04/2003 and is now applied to new claims 77, 80, 83-102 for the reasons of record and those set forth below.

8. With regard to claims 27-31, 33-37, 64-68, 70-74, Applicants argue that the structural feature common to all members of the claimed genus is SEQ ID NO: 1 and the cDNA contained in ATCC Deposit No. 75844. Thus, according to Applicants, one of skill in the art would be able to readily envision and identify sequences of at least 50 contiguous nucleotides of SEQ ID NO: 1 and the cDNA contained in ATCC Deposit No. 75844. Also, Applicants argue that claims 103-126 claim a product by function and that nothing more than a basic knowledge of the genetic code and what is described in the specification is required to identify all the species claimed. As such, Applicants submit that these claims are adequately described. Applicants refer to the references cited by the Examiner in a previous Office Action and assert that an evaluation of function is not germane to the question of whether the written description requirement has been satisfied.

9. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 27-31, 33-37, 64-68, 70-74 or to avoid the rejection of new claims 77, 80, 83-102, 115, 117, 119-126. While it is agreed that (1) the specification discloses the structure of SEQ ID NO: 1 and teaches that the polynucleotide of SEQ ID NO: 1 is contained in the ATCC Deposit No. 75844, and (2) the genus of polynucleotides claimed must share structural elements contained in SEQ ID NO: 1 (or the cDNA in ATCC Deposit No. 75844), the Examiner disagrees with Applicant's contention that the entire genus of nucleic acids claimed is adequately described or that an evaluation of function is not germane to

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the question of whether the written description requirement has been satisfied. Claims 27-31, 33-34, 64-68, 70-71 are not only directed to fragments of the polynucleotide of SEQ ID NO: 1, i.e. polynucleotides consisting of fragments of the polynucleotide of SEQ ID NO: 1 as recited, but they are also directed to polynucleotides encoding polypeptides of any function wherein said polynucleotides comprise the recited fragments. Claims 77, 80, 83-87, 91-99 are directed not only to polynucleotides encoding solely polypeptides consisting of amino acids 59-73 or polypeptides consisting of the purine binding motif of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 75844 but they also encompass polynucleotides encoding polypeptides of any function comprising amino acids 59-73 of SEQ ID NO: 1 or the recited motif. As such, claims 27-31, 33-34, 64-68, 70-71, 77, 80, 83-87, 91-99 are directed to a genus of nucleic acids with the potentiality of encoding proteins of diverse functions not disclosed by the specification.

The written description guidelines indicate that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. It is clear from the art cited by the Examiner that the claimed genus of nucleic acids can encompass many functions. Thus, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

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In regard to claims 115, 117, 119-123, while the polypeptide encoded by the claimed polynucleotide must have HPRT-2 activity, it is noted that items (b) and (d) of claim 115 only require amino acids 59-73 of SEQ ID NO: 2 or the purine binding motif of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 75844. No additional part of the polypeptide of SEQ ID NO: 2 is required since, for example, item (b) does not recite "fragment of SEQ ID NO: 2 comprising at least amino acids 59-73 of SEQ ID NO: 2". The specification does not disclose these structural elements as being the only elements required to display HPRT-2 activity and they do not constitute a substantial portion of the genus claimed since the remainder of a polypeptide comprising these structural limitations, i.e. amino acids 59-73 of SEQ ID NO: 2 or purine binding motif, is completely undefined and the specification does not define the remaining structural features for the members of the genus to be selected. In view of the fact that the claims encompass many functionally and structurally unrelated polynucleotides, one cannot reasonably conclude that the disclosure of a single species, i.e. the polynucleotide of SEQ ID NO: 1, is sufficient to adequately describe the claimed invention.

10. Claims 64-68 and 70-74 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement regarding a biological deposit.

11. In view of the statement submitted on 3/22/2004 stating that the cDNA contained in ATCC Deposit No. 75844 has been deposited under the Budapest Treaty and that this biological deposit will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, this rejection is hereby withdrawn.

12. Claims 27-31, 33-37, 64-68, 70-74 remain rejected and new claims 77, 80, 83-104, 106, 108-115, 117, 119-126 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (1) a polynucleotide encoding the polypeptide of SEQ ID NO: 2 or the cDNA contained in

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ATCC deposit No. 75844, and (2) polynucleotides consisting of fragments of the polynucleotide of SEQ ID NO: 1 or the cDNA contained in ATCC Deposit No. 75844, does not reasonably provide enablement for (1) a polynucleotide encoding a polypeptide of any function wherein the polynucleotide comprises at least 50 contiguous nucleotides of nucleotides 626-1260 of SEQ ID NO: 1, at least 50 contiguous nucleotides of the cDNA contained in ATCC Deposit No. 75844, (2) a polynucleotide encoding a polypeptide of any function or a polypeptide having HPRT-2 activity wherein the polypeptide comprises amino acids 59-73 of SEQ ID NO: 2 or the purine binding motif of the polypeptide encoded by the cDNA contained in ATCC Deposit No. 75844, (3) a polynucleotide encoding a polypeptide of any function wherein the polypeptide comprises at least 30/50 contiguous amino acids of SEQ ID NO: 2 or 30/50 contiguous amino acids of the polypeptide encoded by the cDNA contained in ATCC deposit No. 75844, (4) a polynucleotide encoding a polypeptide having hypoxanthine phosphoribosyl transferase 2 activity wherein said polypeptide is at least 90% sequence identical to SEQ ID NO: 2, (5) host cells comprising the polynucleotides of (1)-(4), or (6) methods to recombinantly produce the proteins encoded by the polynucleotides of (1)-(4). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection has been discussed at length in a previous Office Action mailed on 12/04/2003 and is now applied to new claims 77, 80, 83-104, 106, 108-114 for the reasons of record and those set forth below.

13. Applicants argue that in view of the teachings of the specification regarding how to detect HPRT-2 activity and basic knowledge of the genetic code, one of skill in the art can make and use every single species claimed. Applicants also submit that the specification describes the uses of the claimed polynucleotide fragments and that the use of these fragments do not require a retention of biological activity. Applicants refer to *In re Wands* and assert that the present specification provides more than ample guidance to those of ordinary skill in the art for how to make and use the claimed polynucleotides.

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14. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection of claims 27-31, 33-37, 64-68, 70-74 or to avoid the rejection of new claims 77, 80, 83-104, 106, 108-115, 117, 119-126. While the Examiner agrees that detecting HPRT-2 activity is known and the use of fragments of the polynucleotide of SEQ ID NO: 1 as probes has been disclosed, the Examiner disagrees with Applicant's contention that basic knowledge of the genetic code and the teachings of the specification is all that is required to practice the claimed invention or that the specification provides ample guidance to practice the claimed invention, like *In re Wands*. As indicated above, claims 27-31, 33-34, 64-68, 70-71, 77, 80, 83-87, 91-99 are directed not only to fragments of the polynucleotide of SEQ ID NO: 1 (or the cDNA of ATCC Deposit No. 75844) but to a genus of nucleic acids with the potentiality of encoding proteins of diverse functions not disclosed by the specification. As evidenced by the art cited previously by the Examiner, determining function using structural homology alone without any guidance as to a correlation between structure and function is unpredictable. Thus, one of skill in the art would have to go through the burden of undue experimentation in order to determine which of the polynucleotides having the structural characteristic recited encode polypeptides having HPRT-2 activity, and determining the actual function of those polynucleotides which do not encode polypeptides having HPRT-2 activity. Therefore, in view of what is known in the art and what is required to practice the claimed invention, one cannot reasonably conclude that all that is required to practice the claimed invention is routine experimentation, as it was found in *In re Wands*.

With regard to claims 103-104, 106, 108-111, 115, 117, 119-123, while there is a recitation of function associated with the claimed polynucleotides, it is noted that (1) the specification does not teach that amino acids 59-73 of SEQ ID NO: 2 or the purine binding motif is all that is required to display HPRT-2 activity, and (2) there is no teaching in the specification as to which amino acids can be modified in the polypeptide of SEQ ID NO: 2 to create structural homologs having the same activity as that of the polypeptide of SEQ ID NO: 2, i.e. HPRT-2. Since amino acids 59-73 of SEQ ID NO: 2 or the purine

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binding motif are not structural elements associated with HPRT-2 activity, and the specification does not disclose the structural elements required in any polypeptide having HPRT-2 activity, one of skill in the art would have no clue as to which structural elements in addition to those recited are required to display HPRT-2 activity. Furthermore, while one could argue that the level of sequence variability recited is not likely to affect function, it is noted that Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) and Witkowski et al. (Biochemistry 38:11643-11650, 1999) clearly teach that even structural homologs having more than 90% sequence identity do not share the same function. Therefore, in view of the information disclosed by the specification, the examples provided, and the unpredictability of the art regarding structure and function, one cannot reasonably conclude that the claimed invention is fully enabled by the teachings of the specification.

Double Patenting

15. Claims 27-31, 33-37, 64-68, 70-74 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of copending Application No. 09/189833.

16. In view of the fact that the claims in U.S. Patent No. 6653446 (Application No. 09/189833) are directed to the polypeptide of SEQ ID NO: 2 and polynucleotide claims in Application No. 09/189833 were restricted, this rejection is hereby withdrawn.

Allowable Subject Matter

17. Claims 78-79, 81-82, 105, 107, 116, 118 appear to be allowable over the prior art of record but are objected to since they depend upon a rejected base claim.

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Conclusion

18. No claim is in condition for allowance.

19. Applicant's amendment of claims 27, 29, 64, 66 and addition of claims 77-126 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

20. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 28, 2004



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